



ENVIRONMENTAL PROTECTION AGENCY

[FRL-9957-50-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

DATES: A public virtual meeting will be held on January 25-26, 2017, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate, subsequent teleconference meeting is planned for Thursday, March 17, 2017, from 2:00 p.m. to approximately 3:30 p.m. for the HSRB to finalize its Final Report of the January 25-26, 2017 meeting and review other possible topics.

ADDRESSES: Both of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information visit the HSRB Website:

<http://www2.epa.gov/osa/human-studies-review-board>

FOR FURTHER INFORMATION, CONTACT: Any member of the public who wishes to receive further information should contact the HSRB Designated Federal Official (DFO), Jim Downing on telephone number (202) 564-2468; fax number: (202) 564-2070; email address: downing.jim@epa.gov; or mailing address: Environmental Protection Agency, Office of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Meeting access: These meetings are open to the public. The full Agenda and Meeting materials are available at the HSRB Website: <http://www2.epa.gov/osa/human-studies-review-board>. For questions on document availability, or if you do not have access to the Internet, consult with the DFO, Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact the DFO listed under FOR FURTHER INFORMATION CONTACT at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

How May I Participate in this Meeting?

The HSRB encourages the public's input. You may participate in these meetings by following the instructions in this section.

1. Oral comments. Requests to present oral comments during either conference call will be accepted up to Noon Eastern Time on Wednesday, January 18, 2017, for the January 25-26, 2017 meeting and up to Noon Eastern Time on Friday, March 10, 2017 for the March 17, 2017 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during either call at the designated time on the agenda. Oral comments before the HSRB are generally limited to five minutes per individual or organization. If additional time is available, further public comments may be possible.

2. Written comments. Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Wednesday, January 18, 2016, for the January 25-26, 2017 conference call, and by noon Eastern Time on Friday, March 10, 2017 for the March 17, 2017

teleconference. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments to the DFO, Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research that are submitted to the Office of Pesticide Programs to be used for regulatory purposes. The major objectives of the HSRB are to provide advice and recommendations on: (1) research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research.

Topics for discussion. On Wednesday, January 25, 2017, EPA's Human Studies Review Board will consider three published articles:

1. Methylisothiazolinone contact allergy and dose-response relationships, authored by Michael D. Lundov, Claus Zachariae, and Jeanne D. Johansen. *Contact Dermatitis* (2011) 64, 330-336.
2. Methylisothiazolinone in rinse-off products causes allergic contact dermatitis: a repeated open-application study, authored by K Yazar, M. D. Lundov, A. Faurschou, M. Matura, A. Boman, J. D. Johansen, and C. Lidén. *British Journal of Dermatology* (2015) 173, 115-122.
3. An evaluation of dose/unit area and time as key factors influencing the elicitation capacity of methylchloroisothiazolinone/methylisothiazolinone (MCI/MI) in MCI/MI-allergic patients, authored by Claus Zachariae, Anne Lerbaek, Pauline M. McNamee, John E. Gray, Mike Wooder, and Torkil Menné. *Contact Dermatitis* (2006) 55, 160-166.

Then on Thursday, January 26, 2017 the HSRB will consider:

1. Published article: Cholinesterase Activity Resulting from Carbaryl Exposure.
2. Unpublished article: A randomized double blind study with malathion to determine the residues of malathion dicarboxylic acid (DCA), malathion monocarboxylic acid (MCA), dimethyl phosphate (DMP), dimethyl thiophosphate (DMTP), and dimethyl dithiophosphate (DMDTP) in human urine.

Meeting materials for these topics will be available in advance of the meeting at

<http://www2.epa.gov/osa/human-studies-review-board>.

On March 17, 2017, the Human Studies Review Board will review and finalize their draft Final Report from the January 25-26, 2017 meeting in addition to other topics that may come before the Board. The HSRB may also discuss planning for future HSRB meetings. The agenda and the draft report will be available prior to the conference call at <http://www2.epa.gov/osa/human-studies-review-board>.

Meeting minutes and final reports. Minutes of these meetings, summarizing the matters discussed and recommendations made by the HSRB, will be released within 90 calendar days of the meeting. These minutes will be available at <http://www2.epa.gov/osa/human-studies-review-board>. In addition, information regarding the HSRB's Final Report, will be found at <http://www2.epa.gov/osa/human-studies-review-board> or from Jim Downing listed under FOR FURTHER INFORMATION CONTACT.

Dated: December 19, 2016.

Thomas A. Burke,
EPA Science Advisor

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